In the United States Court of Federal Claims office of special masters

No. 19-1685V UNPUBLISHED

SHARON STEPHENS,

Petitioner,

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SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: September 15, 2021

Special Processing Unit (SPU); Findings of Fact; Onset; Ruling on Entitlement; Influenza (Flu); Shoulder Injury Related to Vaccine Administration (SIRVA).

Maximillian J. Muller, Muller Brazil, LLP, Dresher, PA, for Petitioner.

Sarah Christina Duncan, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT¹

On October 30, 2019, Sharon Stephens filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the "Vaccine Act"). Petitioner alleges that as a result of her influenza ("flu") vaccine on August 29, 2018, she suffered a shoulder injury related to vaccination ("SIRVA") as defined on the Vaccine Injury Table (the "Table"). Petition (ECF No. 1) at Preamble. The case was assigned to the Special Processing Unit of the Office of Special Masters.

¹ Because this unpublished opinion contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the opinion will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

For the reasons discussed below, I find that the preponderance of evidence supports the conclusion that Petitioner suffered the onset of shoulder pain within 48 hours after vaccination, and that Petitioner is entitled to compensation for a right SIRVA.

I. Relevant Procedural History

On October 7, 2020, Respondent provided an informal review of the case, maintaining that the medical records contained some support for an onset of shoulder pain occurring well outside of the Table's 48-hour timeframe. ECF No. 15. I then afforded Petitioner 75 days to file any available affidavits from third-party witnesses and/or available non-medical evidence to bulwark onset. ECF Nos. 16-17. Petitioner was unable to obtain any such evidence. ECF No. 18.

On March 29, 2021, Respondent formally opposed compensation, on the grounds that Petitioner had not established the onset of shoulder pain began within 48 hours of vaccination. Rule 4(c) Report (ECF No. 20) at 5-6. On June 23, 2021, I afforded the parties 60 days to file any briefing and any other relevant evidence pertaining to the onset of Petitioner's alleged injury. ECF No. 21. Neither party made any filings. This matter is now ripe for adjudication.

II. Relevant Factual Evidence

I have fully reviewed the evidence, including all medical records and affidavits, Respondent's Rule 4(c) Report, and the parties' briefing. I find most relevant the following:

- Upon receiving the subject vaccination, Petitioner was sixty-seven (67) years old, retired, and living independently in San Bernardino County, California. Ex. 2 at 610, 1069; Ex. 5 at 4.
- Petitioner received regular medical care through the Kaiser Permanente health maintenance organization ("HMO"). The medical records do not reflect any complaints of left shoulder pain in the three years prior to vaccination.³ See generally Ex. 2.

³ Petitioner had a history of bilateral frozen shoulder at least a decade before vaccination. See Ex. 2 at 1107, 1287 (subsequent medical records). She avers, however, that this pain was "completely different" and "not the same syndrome or related to the pain" she sustained following the August 29, 2018, flu vaccine. Ex. 4 at ¶ 14 (Petitioner's affidavit).

- On August 29, 2018, Petitioner presented to her primary care doctor for concerns for sun damage and fatigue. Ex. 2 at 1063-69. The doctor examined her skin and did not see any concern for pre-cancerous lesions. *Id.* at 1066. A nurse administered the flu vaccine via intramuscular injection to Petitioner's left deltoid. *Id.* at 1069; Ex. 1 at 1.
- On August 30, 2018, after receiving electronic notification of lab results from her last encounter, Petitioner emailed her primary care doctor to ask about the significance of the findings of elevated microalbumin and creatinine levels. Ex. 2 at 1092. A different doctor responded that those results were only mildly elevated but associated with kidney function, which was commonly impacted by diabetes and high blood pressure. *Id.* at 1091.
- On September 17, 2018, Petitioner had a follow-up telephone appointment encounter with her gastroenterologist about an ongoing concern unrelated to her shoulder. Ex. 2 at 1100-01.
- Seventy (70) days post-vaccination, on November 7, 2018, Petitioner returned to her primary care practice. The nurse recorded Petitioner's chief complaint as: "Shoulder pain: left x3 weeks since flu vaccine." Ex. 2 at 1106. Her doctor separately recorded Petitioner's concern of "shoulder pain and possibly recurrent frozen shoulder triggered by flu shot." *Id.* at 1107. The doctor observed left shoulder weakness, decreased range of motion, and pain on abduction. *Id.* at 1108. He "encouraged [Petitioner] to continue annual flu vaccination; although I can[not?] say for sure not due to flu shot, it is unlikely, and the benefits of flu vaccinations outweigh the risks." *Id.* at 1108. He ordered an x-ray (which was completed later that day, with unremarkable findings), prescribed the muscle relaxant meloxicam, also recommended non-prescription NSAIDs and acetaminophen, and referred to physical therapy for gentle stretching and improved range of motion. *Id.*
- On November 28, 2018, Petitioner had an initial physical therapy consult for "L shoulder pain and reduced mobility s/p flu shot injection on 08/29/18 likely due to adhesive capsulitis." Ex. 3 at 35. She was assessed to have 52.27% disability, pain with activity rated at 8/10, decreased range of motion, decreased strength, and mild to severe difficulty with various daily tasks. *Id.* at 35-36, 38. She attended another five physical therapy sessions, on a weekly basis, concluding on January 10, 2019. *Id.* at 35-80.
- On February 6, 2019, Petitioner presented to an acupuncture specialist seeking treatment for a "sore shoulder since flu shot Aug 2018," with

worsening pain, currently reaching 7/10. Ex. 5 at 5-7. The provider planned a total of 10 sessions of acupuncture and cupping,⁴ but Petitioner only underwent the first session and never returned. *Id.* at 6.

- On February 13, 2019, during an annual wellness exam, Petitioner complained of ongoing left shoulder pain despite attending physical therapy and taking NSAIDs. The primary care doctor entered a referral to an orthopedic surgeon. Ex. 2 at 1222-29, 1242.
- On February 22, 2019, Petitioner presented to the orthopedic surgeon, whose specialties are listed in the medical records as sports medicine and shoulder surgery. The orthopedic surgeon recorded Petitioner's history of bilateral frozen shoulder, as well as more recent "low grade pain" that was not associated with any "frank injury event." Ex. 2 at 1287. After conducting a physical exam and reviewing the prior x-ray, the orthopedic surgeon assessed left shoulder joint pain and osteoarthritis with positive impingement signs. *Id.* at 1287-93. He planned prescription NSAIDs (oral and topical), "inject if deteriorates," and "MRI if refractory." *Id.* at 1293. He also discussed potential surgical intervention (e.g., repair of the rotator cuff and/or biceps tendon) may be indicated. *Id.*
- Upon returning to physical therapy on March 5, 2019, and again on March 12, 2019, Petitioner reported that her left shoulder felt "pretty good." She had mildly increased left scapular mobility, but continued restrictions in range of motion, weakness, and pain. In addition, Petitioner noted increased pain in her *right* shoulder and that she planned to "see ortho to discuss sharp pains going down R side of body." Ex. 3 at 84-87.
- Petitioner was formally discharged from physical therapy after failing to appear for any further sessions. Ex. 3 at 92, 94.
- The filed Kaiser Permanente records dated through June 20, 2019, reflect that Petitioner had a subsequent telephone encounter with the primary care doctor for the results of cardiac stress tests, as well as correspondence with her established endocrinologist and ophthalmologist. See generally Ex. 2 at 1293-1380. There are no further records filed in this case pertaining to the alleged left shoulder injury.

4

⁴ Cupping is defined as "the application of a small glass or bamboo cup to the skin, after exhausting the air from within it to create a vacuum, in order to draw blood and lymph to the surface of the body and increase local circulation; currently used in Chinese medicine." *Dorland's Medical Dictionary Online*, at https://www.dorlandsonline.com (hereinafter "*Dorland's*").

- In her affidavit, Petitioner recalls that "after" the flu vaccine, her left shoulder was "very sore," which she initially thought was normal and would subside. Ex. 4 at ¶ 2. After a few days, the pain subsided somewhat in intensity, but continued particularly with certain movements. Id. She "just lived with" the pain for a couple of months before concluding that it was not getting better on its own and she needed to seek medical attention. Id.
- Petitioner does not address the nurse's notation that her shoulder pain had been present for "x3 weeks since flu vaccine." See Ex. 2 at 1106.
- Petitioner recalls telling her primary care doctor that she was having "lingering pain that originated from her last flu shot," but that the doctor was dismissive of that connection. Ex. 4 at ¶ 5.5
- Petitioner recalls that she also reported her "lingering pain from a flu shot" to the orthopedic surgeon, but he refused to acknowledge the potential for such an injury and attributed her shoulder pain to osteoarthritis, which, at her age, she would just have to live with. Ex. 4 at ¶¶ 11-13.6
- Petitioner recalls being frustrated that the physical therapy and acupuncture treatment seemed to aggravate, rather than relieve, her pain; that her doctors dismissed her concern that her shoulder injury was caused by the vaccine; and that the Kaiser Permanente HMO's apparent philosophy was that "saving money is more important than the patient's well-being." Ex. 4 at ¶¶ 7-9, 15-17, 20.

⁵ As noted above, the primary care doctor did record Petitioner's concern about the vaccine. He thought that was an "unlikely" cause of her pain, he but could not "say for sure." Ex. 2 at 1108.

⁶ Petitioner avers that upon dismissing her concerns, the orthopedic surgeon displayed "all [her] past x-rays, scans, etc..... none related to the left shoulder that I had the shot in." Ex. 4 at ¶ 13 (emphasis in the original). But as noted above, the orthopedic surgeon reviewed the x-ray of the left shoulder, which was unremarkable, and did support Petitioner undergoing an MRI if her left shoulder injury proved to be "refractory."

⁷ Petitioner avers that for example, a Kaiser Permanente endocrinologist initially failed to document and evaluate a thyroid nodule which proved to be cancerous. Ex. 4 at ¶ 17. The filed medical records reflect that Petitioner was indeed diagnosed with papillary thyroid cancer and underwent a total thyroidectomy in May 2006. But afterwards, she switched endocrinologists and appeared to be satisfied with her care. Repeated thyroglobulin tests and neck ultrasounds were stable with no evidence of cancer recurrence, in the 10 years leading up to the events in question here. *See, e.g.*, Ex. 2 at 1359-65. While Petitioner has established her entitlement to compensation, there is not evidence that the treating providers egregiously prevented evaluation or treatment of her injury.

• Petitioner recalls experiencing significant shoulder pain, limitations in function, and disrupted sleep for "many months." Ex. 4 at ¶ 18. She avers that upon completing her affidavit,⁸ the pain had subsided to the point that it no longer affected her sleep, but she had "lingering" pain where the shot was administered with certain movements and she still had limitations in lifting items. *Id.* But as noted above, the medical records do not document a left shoulder injury continuing beyond March 12, 2019.

III. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, at *19. And the Federal Circuit recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Human Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

The United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events

⁸ While Petitioner's affidavit was not dated or notarized, it was filed on October 30, 2019.

when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] ... did in fact occur within the time period described in the Vaccine Injury Table." *Id.*

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing § 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

IV. Findings of Fact Regarding Onset

The record contains preponderant evidence that Ms. Stephens developed left shoulder pain within 48 hours after vaccination.

In the period between the date of Ms. Stephens's vaccination and her first attempt at treatment, she had two communications with medical providers during which she could have addressed her shoulder issues. But I do not find the omission of shoulder complaints in these communications to undermine a favorable onset determination. The first such communication was to her primary care provider (who had ordered the vaccine), and it is somewhat reasonable to presume that Petitioner would have reported significant shoulder pain to her primary care provider had she then been experiencing a problem. However,

that communication occurred only one day after the vaccination, and Petitioner explains that she was accustomed to having some degree of pain in the shoulder and neck area for a few days after flu shots. Ex. 4 at ¶ 3. The second communication in mid-September is less troubling, since it is not obvious that an individual would report shoulder pain during a focused visit for gastrointestinal issues. Moreover, these two encounters – one email thread and one (albeit scheduled) telephone call – are afforded a lower presumption of accuracy and completion, given that the providers could not observe or examine the patient in person, but were limited to evaluating the complaints which she chose to relay.

In contrast, seventy (70) days after vaccination, Petitioner returned to her primary care practice for a specific complaint of left shoulder pain, at which point the nurse did not record a particularly clear date of onset. A notation of only: "shoulder pain: left x3 weeks" would certainly present a closer question. However, the nurse wrote: "shoulder pain: left x3 weeks *since flu vaccine*." Ex. 2 at 1106 (emphasis added). Thus, an association with the vaccination is made, and it cannot otherwise be ascertained from this record if the intent was to deem onset to have begun three weeks after vaccination, as Respondent proposes. Moreover, the primary care doctor, the physical therapist, and the acupuncturist all accepted Petitioner's account that her shoulder pain began *upon* vaccination. These medical records, as supplemented by Petitioner's affidavit, thus represent preponderant evidence that her onset of shoulder pain was within 48 hours after vaccination.

V. Other Table Requirements and Entitlement

In light of the lack of other objections and my own review of the record, I find that Petitioner has established the other requirements for a Table SIRVA claim. Specifically, there is not a history of prior shoulder pathology that would explain her injury. 42 C.F.R. § 100.3(c)(3)(10)(i). There is no evidence of any other condition or abnormality that represents an alternative cause. 42 C.F.R. § 100.3(c)(3)(10)(ii). The medical records and affidavits support that her shoulder pain and reduced range of motion were limited to the left shoulder. C.F.R. § 100.3(c)(3)(10)(iv). The contemporaneous vaccination record reflects the site of administration as her left deltoid. Ex. 7; Sections 11(c)(1)(A) and (B)(i). Petitioner has not pursued a civil action or other compensation. Ex. 1 at ¶ 12; Section 11(c)(1)(E). Finally, Petitioner suffered the residual effects for more than six months after vaccination. Thus, Petitioner has satisfied all requirements for entitlement under the Vaccine Act.

VI. Conclusion

The case shall now proceed to the damages phase. However, in formulating her demand, Petitioner should recognize the 70-day delay in reporting her injury to any medical provider, her relatively limited treatment, and the lack of medical documentation of a shoulder injury persisting beyond the last physical therapy session (just 6 months and 12 days after vaccination).

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master